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Appl. No. 09/927,006
Amdt. Dated December 9, 2003
Reply to Office Action of July 11, 2003

•• REMARKS/ARGUMENTS ••

The Official Action of July 11, 2003 has been thoroughly studied.

By the present amendment independent claim 1 has been changed to recite a peptide or its derivative having anti-angiogenic functionality. This change to claim 1 has been made to emphasize that the peptides/derivatives each have a common functionality, i.e. anti-angiogenic functionality.

This change limits the listed peptides to those that have anti-angiogenic functionality.

In addition to the changes made to claim 1, claims 1-8 have been changed to correct matters related to grammar, syntax and sentence structure.

Claims 9-12 are non-elected claims and therefore remain unchanged.

In the Official Action the Examiner has instituted a Restriction Requirement in which the Examiner has taken the position that claims 1-8 (Group I) are drawn to a peptide and pharmaceutical products thereof and that claims 9-12 (Group II) are drawn to methods of using a peptide pharmaceutical product.

In response to the Restriction Requirement, applicants hereby elect to have claims 1-8 (Group I) examined in the present application.

On page 2 of the Official Action the Examiner has stated that:

If Applicants choose either group I or group II, the Applicants must further elect on protein sequence by SEQ ID NO from the list of patentably distinct sequences of claim 1. The sequences disclosed in claim 1 are different in structure and function, and patentably distinct. Applicants are required under 35 U.S.C. 121 to elect a single

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disclosed species, even though this requirement is traversed. THIS IS NOT A SEPCIES ELECTION.

The Examiner's position that the different peptides listed in claim 1 are "different in structure and function, and patentably distinct" is respectfully traversed.

Moreover the Examiner's position that the election is being made under 35 U.S.C. §121 is respectfully challenged.

35 U.S.C. §121 provides that restriction may be required to one of two or more "independent" and distinct inventions. However, 37 CFR §1.141 provides that a reasonable number of species may still be claimed in one application if the other conditions of the rule are met.

MPEP §802.01 states:

The term "independent" (i.e., not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation, or effect, for example: (1) species under a genus which species are not usable together as disclosed; or (2) process and apparatus incapable of being used in practicing the process.

In the present case the peptides listed in applicants' claim 1 all have similar function and related structures as evidenced by the fact that the anti-angiogenic activities of P4 and P5 shown in applicants' Fig. 6 are essentially consistent with one another. P4 corresponds to the first peptide listed in claim 1, i.e. {4} and P5 corresponds to the third peptide listed in claim 1, i.e. {5}.

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It accordingly is established by experimental evidence that {4} and {5} share a common functionality which is disclosed in applicants' specification.

It is further noted that {4'} is merely the reverse sequence of {4} and {5'} is merely the reverse sequence of {5} so that these peptides share a similar structure.

It is moreover noted that each of the remaining peptides include as a main structural components either {4}, {4'}, {5} or {5'}.

Accordingly, contrary to the Examiner's position, all the listed peptides share a common structure and function.

MPEP §803 states:

If the search and examination of an entire application can be made without serious burden, the examiner **must** examine it on the merits, even though it includes claims to independent or distinct inventions.

In the present situation, it is submitted that there would be no burden on the Examiner to search both {4} and {5} electronically and any derivatives of these peptides.

37 CFR §1.141 provides that more than one species of an invention can be claimed in a single application provided that the application includes a claim generic to all the claimed species.

MPEP 803.02 states:

If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner **must** examine all claims on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.

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MPEP 803.04 states:

... to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of 37 CFR§1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application. See Examination of Patent Applications Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996).

It has been determined that normally ten sequences constitute a reasonable number for examination purposes. Accordingly, in most cases, up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction. In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Applicants' peptides {4} and {5} include 11 amino acid groups. It is submitted that conducting a search on these peptides and their derivatives and reviewing such search results would not be a burden on the Examiner.

Moreover, a much greater burden would be imposed on applicants should the Examiner maintain what is actually an Election of Species Requirement (although denied by the Examiner), and force applicants to file a series of individual patents to cover the similar peptides which applicants have discovered provide a common anti-angiogenic functionality.

The Examiner has not established on the record that the listed peptides are "independent" and therefore properly restrictable. Applicants submit that the listed peptides are not independent and not distinct from one another for purposes of examination.

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The Examiner is respectfully requested to reconsider and withdrawal the Election of Species Requirement and examine claims 1-8 in the present application.

Notwithstanding applicants' contention that the Election of Species Requirement is improper and should be withdrawn, applicants acknowledge that to be fully responsive, they are required to elect one of the peptides listed in claim 1.

Accordingly, applicants hereby elect {4} and request that the Examiner consider examining both peptides {4} and {5} based upon the similar functionality shown in Fig. 6.

It is believed that the above represents a complete response to the Official Action and reconsideration is requested.

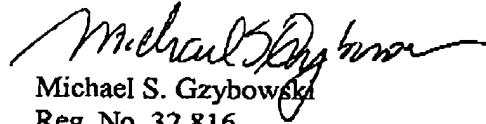
If upon consideration of the above, the Examiner should feel that there remains outstanding issues in the present application that could be resolved, the Examiner is invited to contact applicants' patent counsel at the telephone number given below to discuss such issues.

To the extent necessary, a petition for an extension of time under 37 CFR §1.136 is hereby made. Please charge the fees due in connection with the filing of this paper, including extension of

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time fees, to Deposit Account No. 12-2136 and please credit any excess fees to such deposit account.

Respectfully submitted,


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